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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Laurence Hermitte

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9889

466

7590

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EXAMINER

WESTERBERG, NISSA M

ART UNIT

PAPER NUMBER

1618

MAIL DATE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/565,442	Applicant(s) HERMITTE ET AL.	
	Examiner Nissa M. Westerberg	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 August 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12 - 31 is/are pending in the application.
- 4a) Of the above claim(s) 14, 18 - 20, 22, 24, 27, 30 and 31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12, 13, 15 - 17, 21, 23, 25, 26, 28 and 29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants' arguments, filed August 29, 2008, have been fully considered but they are not deemed to be fully persuasive. The following rejections and/or objections constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 112 1st Paragraph

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 12, 13, 15 – 17, 21, 23, 25, 26, 28 and 29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention because of “non-polymeric chains having antioxidant properties or properties for inhibiting reactions of degradation of said matrix” (lines 10 – 12). This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed May 9, 2008 and those set forth below.

Applicant traverses this rejection by stating “that any type of activity is useful to inhibit degradation of the polymer matrix” (p 14, ¶ 3). Cyclic molecules prevent

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degradation by a steric factor which physically masks sensible sites where the degrading agent would attack. Thus, applicant has disclosed relevant identifying characteristics and the functional characteristics coupled with a known or disclosed correlation between structure and function. The specification describes in detail the use of vitamin C, vitamin A, melatonin etc., demonstrating reduction to practice.

These arguments are not found to fully persuasive. "Cyclic molecules" is one species within the genus of non-polymeric compounds with properties for inhibiting reactions of degradation of said matrix that is described by Applicant. Applicant has asserted that any type of activity is useful to inhibit the degradation of the matrix, an extremely broad statement. A molecule with an activity of generating radicals would seem to promote the degradation of the matrix, not inhibit the degradation, contradicting the statement of Applicant. Arguments without factual support for any activity being able to fall within the limitation of "inhibiting reactions of degradation of said matrix" are mere allegations and are not found to be persuasive. Given Applicants admission that any cyclic molecule will provide the appropriate function, the written description provision for this species is met, but the full breadth of the genus "non-polymeric chains having properties for inhibiting reactions of degradation of said matrix" does not fully comply with the written description provision.

Claim Rejections - 35 USC § 112 2nd Paragraph

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 12, 13, 15 – 17, 21, 23, 25, 26, 28 and 29 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention because non-polymeric chains that possess certain properties can be grafted to the polymer of natural origin in the matrix material are claimed but polymeric compounds are exemplified as being part of the this group. This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed May 9, 2008 and those set forth below.

Applicant traverses this rejection on the grounds that while enzymes are polymers, they differ from the polymers of the matrix in that they are polymers of specific and different monomers (amino acids) whereas the polymers of the matrix are homopolymers or copolymers of repetitive units of a few monomers. Thus, the skilled artisan would readily understand the metes and bounds of the noted claim language.

This is not found to be persuasive. Enzymes are polymers, in which monomers are joined together to form a macromolecule. Whether or not something is a polymer is not dependent on whether or not the material is comprised of only a few (presumably different) monomers rather than specific and different monomers. It is not stated in Applicant's arguments, but it appears that what Applicant may be arguing is that as there are 20 different, naturally-occurring amino acids that can form a protein enzyme and the polymers of the matrix do not necessarily have fewer repeating units, but that only a few different types of monomers are present. Even this argument would not be persuasive

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as ribozymes and made from RNA, which utilizes four naturally occurring monomers (adenosine, uracil, cytosine and guanine) and are produced in cells, rendering them a biocompatible polymer of natural origin. The Examiner was not able to locate any limitation of the number of chemically different monomers comprising for the biocompatible polymer of natural origin in the specification.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

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were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 12, 13 and 17 were rejected under 35 U.S.C. 103(a) as being unpatentable over Nguyen (EP 0 749 982 A1). This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed May 9, 2008 and those set forth below.

Applicant traverses this rejection on the grounds that Nguyen does not disclose the same grafted polymer. In Nguyen, the rate of grafting is limited to 1 equivalent of antioxidant per 10 equivalents of polysaccharide, preferably 1 equivalent to 400 units, values which are much lower than the grafting rate of 10 – 40% of independent claim 12. While one skilled in the art might eventually assume that an increase in the grafting rate will increase the resistance to degradation, Nguyen clearly did not suggest such, especially in view of the preferred values in Nguyen are significantly lows. After reading Nguyen, one would wonder about the consequences of the grafting on the visco-elastic properties of the final product as he would know that an increases the viscosity of the final product which thus decreases its injectability. Grafting chains, even with the molecular weight being less than 50,000 Da could be considered as an increase in cross-linking and the expected results would be an increase in the viscosity beyond the

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limit due to its injectability. Therefore, the matrix of claim 12 achieves surprising and unexpected results over Nguyen, whose teachings are not predictive of the claimed invention so there is no reasonable expectation of success.

These arguments are not found to be persuasive. Claim 12 does not positively recite a quantity of grafting from 10 – to 40%, but merely defines the term. However, even if the range was positively recited, the upper limiting of the grafting in Nguyen is 10% (1 equivalent antioxidant per 10 equivalents of polysaccharide repeating unit). A prima facie case of obviousness exists when overlapping ranges are present (MPEP 2144.05 I).

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the viscosity, the ability to be injected and resistance to degradation) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). While the viscosity and moles of cross-linker for either solid or injectable products is recited in other claims currently under examination, none of the claims to which this particular rejection are being applied contain limitations regarding the injectability or the viscosity of complex matrix. Non-polymeric chains having properties for inhibiting reactions of degradation of said matrix can, but are not required to be present in the matrix but the final material is not required to be resistant to degradation.

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Grafting and cross-linking describe different polymer architecture. In grafting, side chains are attached to one polymer backbone but not to the backbone of a different polymer molecule. Cross-linking requires that the backbones of two different polymer molecules be joined. Grafting higher levels of small antioxidant molecule such as vitamin C would result in a smaller increase in the viscosity of the final material than increasing the degree of cross-linking to the same extent with a cross-linker of similar molecule weight, as grafting does not result in covalent linkages between different polymer molecules. Therefore, given the evidence that is currently on the record, the ability of an increase in grafting to not significantly increase the viscosity of the final product is not unexpected

9. Claims 12, 13, 16, 23, 26 and 29 were rejected under 35 U.S.C. 103(a) as being unpatentable over Nguyen as applied to claims 12, 13 and 17 above, and further in view of Ramamurthi et al. (J Biomed Mater Res 2002). This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed May 9, 2008 and those set forth below.

Applicant has argued that Nguyen fails to teach the grafting rate which constitutes the novel and inventive step discussed above and the teachings of the secondary reference relied upon for the disclosing divinylsulfone cross-linked based polymers is not relevant.

This is not found persuasive because as discussed above, Nguyen does not contain a deficiency regarding the grafting rate.

10. Claims 12, 13, 15 and 21 were rejected under 35 U.S.C. 103(a) as being unpatentable over Nguyen as applied to claims 12, 13 and 17 above, and further in view of Bolotin (PGPub 2003/0224974). This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed May 9, 2008 and those set forth below.

Applicant has argued that Nguyen fails to teach the grafting rate which constitutes the novel and inventive step discussed above.

This is not found persuasive because as discussed above, Nguyen does not contain a deficiency regarding the grafting rate.

11. Claims 12, 15, 25 and 28 were rejected under 35 U.S.C. 103(a) as being unpatentable over Nguyen and Bolotin, further in view of Ramamurthi et al. This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed May 9, 2008 and those set forth below.

Applicant has argued that Nguyen fails to teach the grafting rate which constitutes the novel and inventive step discussed above.

This is not found persuasive because as discussed above, Nguyen does not contain a deficiency regarding the grafting rate.

Conclusion

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

13. This application contains claims 14, 18 – 20, 22, 24, 27 30 and 31 drawn to an invention nonelected with traverse in the reply filed on February 29, 2008. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nissa M. Westerberg whose telephone number is (571)270-3532. The examiner can normally be reached on M - F, 8 a.m. - 4 p.m. ET. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

NMW